

TRIAL/PROGRAM STATUSES – 6th APRIL 2022

[Ovarian Cancer FSHR-Mediated CER-T Ph 1 Trial initiated at Moffitt Cancer Center](#)

Jose R. Conejo-Garcia, M.D., Ph.D., Chair of the Department of Immunology at Moffitt Cancer Center and co-inventor of the CER-T technology, added, "CAR-T therapies are rapidly becoming an important player in cancer therapy, and our lab has developed a technology that has the potential to target tumors by using an existing biological mechanism that is well understood. If our CER-T approach is successful, it could serve as a model for future targeted CAR-T therapies in other cancer types. The goal in cancer therapy has always been to kill cancer cells with limited damage to healthy tissue, and we look forward to seeing how this CER-T therapy may be able to accomplish that in solid tumors, which have historically proven challenging to eradicate with cell therapy."

[Monotherapy Patient Received a Transplant in APVO436 Expansion Trial for the Treatment of Acute Myeloid Leukemia](#)

"We are very pleased to report that a refractory secondary AML patient, after receiving APVO436 as monotherapy, experienced a significant reduction in bone marrow blasts, tolerated the treatment well, experienced clinical benefit and was therefore able to proceed to allogeneic transplant. Prior to trial entry, this patient had refractory disease after receiving multiple other lines of therapy and had a very poor prognosis. There were few therapeutic options left with which to fight the disease," said Justin Watts, MD, Associate Professor of Medicine, Chief, Leukemia Section at the University of Miami Sylvester Comprehensive Cancer Center and treating investigator. "Without APVO436, this patient would not have proceeded to transplant, a highly desirable outcome for patients with AML."

[First Patient Dosed in PRECISION 1 Ph 2 Trial of nab-Sirolimus in Patients with Solid Tumors with Pathogenic Inactivating Alterations in TSC1 and TSC2 Genes](#)

"We are excited to have initiated dosing in our PRECISION 1 clinical trial," stated Loretta Itri, M.D., Chief Medical Officer of Aadi. "There are currently no approved treatment options for patients with TSC1 or TSC2 alterations, and this trial is designed to evaluate the efficacy, safety and tolerability of nab-sirolimus to treat patients with tumors driven by those alterations. We believe that the early data we presented at ASCO 2021 from our Expanded Access Program for FYARRO suggested activity of nab-sirolimus in this patient population. In the PRECISION 1 trial, the two arms will be independently evaluable in order to separately assess therapeutic activity of nab-sirolimus in tumors harboring either TSC1 or TSC2 inactivating alterations."

[Enrollment begins in Ph 1/2 Acclaim-2 Clinical Trial of REQORSA™ Immunogene Therapy in Combination with Keytruda® in NSCLC patients](#)

"We are pleased to have opened Acclaim-2 for patient enrollment and expect to promptly begin screening patients for their eligibility to participate in the trial," stated Mark S. Berger, M.D., Chief Medical Officer of Genprex. "This marks an important milestone in our clinical development program for REQORSA as we continue to engage with prestigious clinical trial sites to build patient enrollment and provide hope to lung cancer patients who suffer from this devastating disease and who are in desperate need of new treatment options. We look forward to completing the Phase 1 portion of Acclaim-2 by the end of the first quarter of 2023 and to generating data to show the synergistic effects REQORSA combined with immunotherapies can have in patients."

Ph 1b/2 Study of RBN-2397 in Combination with Pembrolizumab initiated in Patients with Squamous Cell Carcinoma of the Lung

“RBN-2397 is a selective PARP7 inhibitor designed to activate the Type I interferon response in tumor cells and overcome a major limitation of immune checkpoint inhibitors (ICI). Combining RBN-2397 with an anti-PD-1 ICI is expected to treat a variety of tumor types including SCCL, a devastating disease representing the second most common form of non-small cell lung cancer,” said Prakash Raman, Ph.D., President and Chief Executive Officer, Ribon Therapeutics. “The initiation of the Phase 1b/2 study of RBN-2397 with pembrolizumab will enable us to further understand the potential utility of this combination therapy.”